(*a*) If the batch is packaged for repacking or for use in the manufcture of another drug:

(*1*) For all tests except sterility: 10 packages, each containing approximately 500 milligrams.

(*2*) For sterility testing: 20 packages, each containing approximately 300 milligrams.

(*b*) If the batch is packaged for dispensing:

(*1*) For all tests except sterility: A minimum of 14 immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample with sufficient sterile distilled water to obtain a stock solution of convenient concentration; also, if it is packaged for dispensing, reconstitute as directed in the labeling. Then, using a suitable hypodermic needle and syringe, remove all of the withdrawable contents if it is represented as a single dose container; or if the labeling specifies the amount of potency in a given volume of the resultant preparation, remove an accurately measured representative portion from each container. Dilute with sterile distilled water to obtain a stock solution of convenient concentration. Further dilute a portion of the stock solution with sterile distilled water to the reference concentration of 2.5 micrograms of tobramycin per milliliter (estimated).

(2) *Sterility*. Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens*. Proceed as directed in § 436.32(a) of this chapter, using a solution containing 10 milligrams of tobramycin per milliliter.

(4) [Reserved]

(5) *Moisture*. Proceed as directed in § 436.201 of this chapter.

(6) *pH*. Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 40 milligrams per milliliter, or if it is packaged for dispensing, reconstitute as directed in the labeling.

(7) *Identity*. Proceed as directed in § 436.318 of this chapter.

(8) *Residue on ignition*. Proceed as directed in § 436.207(a) of this chapter.

(9) *Heavy metals*. Proceed as directed in § 436.208 of this chapter.

[44 FR 26072, May 4, 1979, as amended at 45 FR 16476, Mar. 14, 1980; 50 FR 19919, May 13, 1985]

Subpart B—Oral Dosage Forms

§ 444.130 Kanamycin sulfate capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Kanamycin sulfate capsules are composed of crystalline kanamycin sulfate, with or without one or more suitable and harmless buffer substances, vegetable oils, preservatives, diluents, binders, lubricants, colorings, and flavorings, enclosed in gelatin capsules. Each capsule contains 500 milligrams of kanamycin. Its potency is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of kanamycin that it is represented to contain. The loss on drying is not more than 4.0 percent. The crystalline kanamycin sulfate used conforms to the standards prescribed by § 444.30(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The kanamycin sulfate used in making the batch for potency, loss on drying, pH, residue on ignition, identity, kanamycin B content, and crystallinity.

(*b*) The batch for potency and loss on drying.

(ii) Samples required:

(*a*) Kanamycin sulfate used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch: Minimum of 30 capsules.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Place a representative number of capsules into a high-speed

glass blender jar with sufficient sterile distilled water to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Remove an aliquot and further dilute with sterile distilled water to the reference concentration of 10 micrograms of kanamycin per milliliter (estimated).

(2) *Loss on drying.* Proceed as directed in §436.200(b) of this chapter.

[39 FR 19046, May 30, 1974, as amended at 50 FR 19919, May 13, 1985]

§444.142 Neomycin sulfate oral dosage forms.

§444.142a Neomycin sulfate tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate tablets are tablets composed of neomycin sulfate with one or more suitable and harmless binders, and with or without one or more suitable and harmless fillers, buffers, lubricants, and colorings. Each tablet contains 150 milligrams, 175 milligrams, or 350 milligrams of neomycin. The moisture content is not more than 10.0 percent. Tablets shall disintegrate within 1 hour. The neomycin sulfate used conforms to the standards prescribed by §444.42a(a)(1)(i), (v), (vi), and (vii). Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter. Its expiration date is 12 months.

(3) *Requests for certification; samples.* In addition to the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The neomycin sulfate used in making the batch for potency, moisture, pH, and identity.

(*b*) The batch for potency, moisture, and disintegration time.

(ii) Samples required:

(*a*) The neomycin sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch:

(*1*) For all tests except disintegration time: Minimum 30 tablets.

(*2*) For disintegration time: Six tablets.

(*c*) In the case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in §444.42a(b)(1), except prepare the sample as follows: Place a representative number of tablets into a high-speed glass blender, add a sufficient quantity of 0.1*M* potassium phosphate buffer, pH 8.0, to give a stock solution of convenient concentration. Blend 3 to 5 minutes. Further dilute in 0.1*M* potassium phosphate buffer, pH 8.0, to the proper prescribed reference concentration. Its neomycin content is satisfactory if it contains not less than 90 percent and not more than 125 percent of the number of milligrams of neomycin that it is represented to contain.

(2) *Moisture.* Proceed as directed in §436.200(b) of this chapter.

(3) *Disintegration time.* Proceed as directed in §440.180a(b)(3) of this chapter.

[39 FR 19046, May 30, 1974, as amended at 46 FR 25608, May 8, 1981; 50 FR 19919, May 13, 1985]

§444.142b Neomycin sulfate oral solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate oral solution is neomycin sulfate with or without one or more suitable and harmless flavorings, colorings, and preservatives in an aqueous vehicle. Each milliliter contains 17.5 milligrams of neomycin. Its potency is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of neomycin that it is represented to contain. Its pH is not less than 5.0 and not more than 7.5. The neomycin sulfate used conforms to the standards prescribed by §444.42a(a)(1)(i), (v), (vi), and (vii).

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on: